

Summary speech by Mr Geert Dancet, ECHA (Interim Executive Director of the European Chemicals Agency)

at the "R" in REACH who has to fulfil what and when? – workshop

21. June 2007, Wissenschaftszentrum, Bonn

Ladies and gentlemen,

Thank you for giving the opportunity to the newly established European Chemicals Agency to round up today's workshop on the R in REACH. Not only am I the sole representative of the ECHA in this workshop, but I also notice that I am the only person in the audience from the Nordic countries here. 21 June or mid-summer day is of course an important day for these countries.

I am grateful to the German presidency for hosting this event which presents a state of play in the development of guidance to industry for pre-registration and registration of chemical substances. I hope that the big interest shown by companies, industry associations and other stakeholders rewards the Presidency for all efforts that went into organization of the workshop.

I hope that the workshop provided information that you as lucky participants can take home and use for your own work to implement REACH or that you can bring to your colleagues, industries or industry associations to inform them about the next steps they need to take under REACH. I encourage you to spread the message.

My colleagues from the Commission and I hope also that after today's event "R in REACH" for you now not only means Registration under REACH, but also

- Relevant information provided
- Rapid access to help and IT; and
- Right understanding of REACH obligations

Bjorn Hansen gave you an overview of where we stand today in implementing REACH and what industry, national authorities and the Commission need to do next.

He concluded that a company that demonstrates in his registration how the chemical substance can be adequately controlled leading to no effect on man or the environment will very likely be an endpoint of its efforts under REACH.

He recognized that there is no doubt that, even with today's information and with all guidance and help, REACH remains an enormous challenge for companies. Lying back

and expecting the guidance and tools to resolve your tasks for you is therefore a wrong expectation. As Jack de Bruijn said, don't expect the guidance to be a GPS.

Jack the Commission's coordinator for the RIP presentation accepted that the content and volume of the guidance is substantial. However, this is necessary because companies have many detailed questions and turn to the Commission and the helpdesks for answers.

He showed the simple tools in the overall guidance package where stakeholders can get quickly a first overview and understanding of REACH. That tool is the "About REACH" section on the ECHA guidance website.

Companies that want to find out about their obligations should use the Navigator tool. This tool gives an individual list of obligations and links to the part of the guidance that companies need to read. The ECHA website is the single point of entry to all these tools.

In this way, the guidance gives a tailor-made service to companies to a large degree in their own language, both for SMEs who in most cases have limited obligations under REACH but have to find out very rapidly what they need to do by when, and for experienced chemical companies with a lot of detailed questions about the registration dossier.

If companies have not already done so, they should urgently make an inventory of substances they are dealing with and find out what role they have under REACH, - whether they are manufacturers, importers, producers of articles, downstream users or distributors. Companies need to be aware of the need to pre-register substances between 1 June and 1 December 2008, if they want to benefit from the transition provisions for phase-in substances.

Mike Rasenberg did his very best to present the RIP 3.10 guidance on substance identity in simple words and principles. For some companies, the identity of their substances is self-evident, for others it is more complicated than he could explain in the short time given. But he also showed that the identity choice is important for the SIEF formation. He stressed how essential the name and identity of the substance is in getting to the SAME substance and in defining who is in the SIEF and who is not.

Otto Linher continued the logic. He was rather inventive in his language bringing some new concepts that can be helpful in the REACH world such as SAMENESS of substances, the SFF or SIEF Formation Facilitator and PRE-SIEF. He stressed that in some cases pre-registration under the same EINECS code does not automatically mean the formation of one SIEF. It is a task for industry to verify the sameness of substances and if necessary form several SIEFs under one EINECS entry or one SIEF for several EINECS entries. This process is difficult to imagine without a consistent approach towards substance identity.

He also explained how SIEF's must and can operate and how REACH-IT will help them. REACH IT will only provide an initial service through the SIEF formation facilitator and the free fields for posting messages on SIEF formation. Yet, he stressed that the Agency will not intervene in the work of SIEFs and that CEFIC is working on a tool that will support the work of SIEF's and consortia. In this context, I also would like to welcome CEFIC's initiative to provide a platform for the operation of SIEFs. Yet, he also stressed the pitfalls in the work of SIEFs such as cost sharing, protection of confidential business information and the respect of competition rules. The bulk of the work of SIEFs ends with the preparation of a joint submission of the data in registrations.

Watzel de Wolf demonstrated how tricky the tasks of industry are under REACH and how the freedoms of the system become colossal challenges in a system of mandatory datasharing and joint submission. He identified 13 challenges between now and registration. He concluded that REACH will be a struggle for substance manufacturers and importers but industry will survive thanks to the miracles of science.

Peter van der Zandt presented the main rules applying to registration. The first series of registrations are due to come in by 30 November 2010. This will involve in particular HPV substances and substances raising particular concern. This will be pioneer work allowing those registering at a later stage to learn from the experience of those who have registered first.

From the first questions and answer session I retain that there are advantages and disadvantages to become lead registrant or co-registrant and that early registrants will not be able to escape their role in the joint submission of data and corresponding data sharing.

Andrea Paetz showed the practical IT tools which can assist companies in gathering, managing and submitting data. She and Cefic are very enthusiastic about IUCLID5, the first IT product delivered on 12 June to the outside world by the European Commission and the Agency. This instrument will not only serve industry to prepare dossiers to comply with REACH but also with other EU legislation on chemicals or the HPV program of the OECD. Perhaps, other countries will also use this tool for requiring compliance with their legislation in the future. She also made clear that there is still a long way to go in getting the other IT tools ready in time such as REACH-IT, the CSR tool and any other tools which Cefic or other industry associations feel are necessary to support the REACH work.

Andreas Ahrens presented the main elements of exposure scenarios and how they can be put into practice. Among the new elements that REACH will bring, exposure scenarios will be an essential method companies need to get accustomed to. This will require communication and close co-operation of all actors in the supply chain, including manufacturers and importers, producers of articles, downstream users and

distributors. There is still a lot work to arrive at good guidance that finds a suitable balance between generic and specific exposure scenarios that suit all sectors.

Frank Wangemann entered into much more detail on the communication in the supply chain. DU need to decide whether they wish to make their own CSA. Information on risk management measures need to be passed on in the form of extended Safety Data Sheets from suppliers to clients. He also stressed that formulators have a critical role to play in this process. In merging the extended SDS's and formulating Risk Management Measures that reach DNEL's and PNEC's. His presentation showed some of the calculations that can be applied to achieve these levels of safety.

It is commonly known that downstream users and in particular SMEs in the supply chains may not be aware of their coming tasks. Therefore, the active and effective communication through all possible channels will be essential to ensure that companies will know about their obligations, and in particular will not miss the deadlines.

Majella Cosgrove showed that Member States Competent Authorities and national helpdesks will have a very important role in raising awareness. It is my view that awareness campaigns should more and more be organized at national level in the language of the companies.

Doris Thiemann's presentation showed you how the Agency is supporting these national helpdesks and how important it is to arrive at harmonized replies to the difficult questions companies will more and more have. Again, an IT tool is the main instrument used to achieve harmonization on a daily basis.

I would also like to underline the important role that industry associations and their helpdesks will play in providing industry specific advice. These two categories of helpdesks should co-operate and understand their different roles. Public helpdesks are there to help companies understand WHAT to do, private helpdesks are there to help companies HOW to comply in practice.

You will have understood today that the RIP projects on the guidance and IT tools are still very much work in progress. The European Commission is pressing its contractors to deliver in time the products under construction. The Agency will over the coming months have to take over these products and in some cases the contracts and has to evaluate the situation at that point in time. Yet, it should not surprise anybody that the guidance and IT tools are perceived as most critical to the success of REACH.

If there were small delays in delivering some of the tools, this is the result of my demand that any Agency product is thoroughly tested before it goes on the market. I also insist over and over again on maximum translation to improve access to information for SMEs.

There should be no doubt that ECHA has a formidable task ahead in the coming months. By 1 September I hope to have the staff in place to start intensive work in preparing Agency procedures and processes, in finishing the integration of the guidance, in completing IT products and in finishing all the other projects and works that allow us to be ready to receive pre-registrations and registrations from 1 June 2008.

The REACH implementation strategy underlines the need for communication and co-operation between companies, but also between companies and authorities. I hope that today's event could be one important milestone in getting this communication and co-operation going. The result should not only be the generation of a lot of new information under REACH but also a safer use of chemicals as well as the creation of confidence among users and consumers of chemicals and products containing these chemicals.

This should demonstrate that REACH is not only a task that needs to be fulfilled for the protection of human health and the environment but that it is also a market opportunity. As Patrick Hennessy has concluded this morning, the winners of REACH will be those who best understand REACH and who are able to find creative and practical solutions to fulfilling their obligations.

I would like to conclude by thanking again the German presidency and all those who contributed to the practical organization of this workshop. Thank you for coming and have a safe trip home.